

STATEMENT OF DAVID A. KESSLER, COMMISSIONER OF FOOD AND DRUGS, FOOD AND DRUG ADMINISTRATION, ACCOMPANIED BY JACK E. HENNINGFIELD, CHIEF, CLINICAL PHARMACOLOGY BRANCH, NATIONAL INSTITUTE ON DRUG ABUSE

Mr. KESSLER. Thank you very much, Mr. Chairman.

The cigarette industry has attempted to frame the debate on smoking as the right of each American to choose. The question we must ask is whether smokers really have that choice. Consider these facts. Two-thirds of adults who smoke say they wish they could quit. Seventeen million try to quit each year, but for every one who quits, at least nine try and fail. Three out of four adult smokers say they are addicted. By some estimates, as many as 74 to 90 percent are addicted. Eight out of 10 smokers say they wish they had never started smoking.

Mr. Chairman, the issue I will address today is simple: Whose choice is actually driving the demand for cigarettes in this country? Is it a choice by consumers to continue smoking? Or is it a choice by cigarette companies to maintain addictive levels of nicotine in their cigarettes?

FDA has not regulated most tobacco products as drugs. One of the obstacles has been a legal one. The law requires an intent that the product be used either in relation to a disease or to affect the structure or function of the human body. Intent is a key word in our statute. We have not had sufficient evidence of such intent with regard to nicotine in tobacco products. The assumption has been that the nicotine in cigarettes is present solely because it is a natural and unavoidable component of tobacco.

Mr. Chairman, that assumption needs to be re-examined. The amount of nicotine in a cigarette may be there by design. Cigarette companies must answer the question, what is the real intent of this design? In my testimony this morning, I will describe some of the information that has prompted our re-examination.

First, I want to address the addictive nature of nicotine. Second, I will talk in some detail about the apparent ability of cigarette companies to control nicotine levels in cigarettes.

My first point is that the nicotine delivered by tobacco products is highly addictive. As the chart shows, that fact is acknowledged by the world's preeminent medical organizations. As with any addictive substance, some people can break their addiction, but I suspect that everyone in this country has seen a friend or relative struggle to extricate himself or herself from a dependence on cigarettes and the nicotine they contain.

Remarkably, we see that nicotine exerts its grip even on patients for whom the dangers of smoking could not be starker. After surgery for lung cancer, almost half of the smokers resume smoking. Even when a smoker has his or her larynx removed, 40 percent try smoking again.

I am equally struck by the statistics about our young people. Seven out of 10 teenage smokers say they believe that they are already dependent on cigarettes. About 4 out of 10 high school seniors who smoke have tried to quit and failed. Most adult smokers today began smoking as teenagers.

It is fair to argue that a decision to start smoking may be a matter of choice. But once people start smoking regularly, most in effect are deprived of the choice to stop smoking. My concern is that the choice that people make at a young age quickly becomes little or no choice at all and it will be very difficult to reverse over the course of their lives.

The primary criteria of addictive substances are compulsive use, a psychoactive effect; that is a direct chemical effect in the brain, and reinforcing behavior that conditions continued use.

Mr. Chairman, nicotine reaches the brain within seconds. This contributes greatly to its reinforcing effect. Nicotine meets all the criteria for an addictive substance. We have learned a great deal about addictive drugs by studying laboratory animals. It is intriguing that with very few exceptions, animals will press levers and do other things to give themselves those drugs that are considered highly addictive in humans, but will not generally self-administer nonaddictive drugs.

Despite being very different chemically, almost all addictive drugs affect the parts of the brain that are important to emotion and motivation. Specifically they affect the regulation of the brain chemical dopamine which produces psychoactive sensation and reinforces drug use behavior.

Animal self-administration is considered a hallmark of a drug with a potential to addict. Nicotine has been shown to affect dopamine release and it has been further shown that animals will self-administer nicotine.

Tobacco industry officials have denied that nicotine is addictive. They use euphemisms—satisfaction, impact, strength to describe the effects of nicotine. But one company states in a quote, "It also has been generally recognized that the smoker's perception of "strength" of the cigarette is directly related to the amount of nicotine contained in the cigarette smoke during each puff."

Euphemisms aside, smokers crave nicotine pure and simple because of its psychoactive effects and its drug dependence qualities. Mr. Chairman, nicotine levels in a cigarettes are more than sufficient to create and sustain addiction in the vast majority of smokers.

Let me turn to my second point today, which involves the control of nicotine levels exercised by the tobacco industry. Mr. Chairman, I do not have all the facts or all the answers today. Certainly practices differ within the industry and the technology available to one company may not be available to another. It is important to keep this in mind. But a picture is beginning to emerge.

The public may think of cigarettes as no more than blended tobacco rolled in paper. But they are more than that. Some of today's cigarettes may in fact qualify as high technology nicotine delivery systems that deliver nicotine in quantities sufficient to create and to sustain addiction in the vast majority of individuals who smoke regularly.

But you don't have to take it from me. Just listen to the words written by a supervisor of research at one of the Nation's largest tobacco companies in 1972. And I quote, "Think of the cigarette pack as a storage container for a day's supply of nicotine. Think of the cigarette as a dispenser for a dose unit of nicotine. Think of a

puff of smoke as the vehicle for nicotine. Smoke is beyond question the most optimized vehicle of nicotine and the cigarette the most optimized dispenser of smoke."

How does the cigarette industry design cigarettes? Several decades ago, the industry began to recognize that nicotine is the psychoactive ingredient in tobacco smoke. Numerous patents since then illustrate how the industry has worked hard to sustain the psychoactive effects of nicotine in cigarettes.

These charts I will show you show examples from several categories of patents. I recognize you can't read them all now, but I wanted to give you a feel for the kinds of patents we are seeing.

Eight patents on the first chart (B) increased nicotine content by adding nicotine to the tobacco rod.

On the next chart (C) five patents are listed to increase nicotine content by adding nicotine to filters, wrappers and other parts of the cigarette.

The next chart (D) shows three patents that use advanced technology to manipulate the levels of nicotine in tobacco.

On the next chart (E) there are eight patents for the extraction of nicotine from tobacco. The next chart (F) shows nine patents to develop new chemical variants of nicotine.

Patents not only describe a specific invention but they can do much more. They speak to the industry's capabilities and research and they provide insight into what industry may be attempting to achieve with its products. At the same time, however, it is prudent to keep in mind that patents do not tell us what processes are currently in use. Nevertheless, the number and pattern of these patents leaves little doubt that the cigarette industry has developed enormously sophisticated methods for manipulating nicotine levels in cigarettes.

Look at the industry's own words in these patents. Let me read the key words from a number of patents. The industry is interested in "maintaining the nicotine content at a sufficiently high level to provide the desired physiological activity, taste, and odor."

These are the words of the patents. "Add nicotine." "Maintaining or increasing the nicotine content." "The release in controlled amounts of nicotine." "Nicotine released in controlled amounts." "Manipulation of the nicotine." "Provide various nicotine levels." "Varying levels of endogenous and exogenous nicotine." "Maintenance of the proper amount of nicotine." "Delivers a larger amount of nicotine." "Nicotine donor." "A process for the migration of nicotine." "Nicotine can be incorporated." "Nicotine-enhanced smoking device." "The application of nicotine components." "Incorporated within the filler material applied to the wrapper, applied within the glue line of the wrapper."

Let me briefly describe how a few of these technologies work. U.S. Patent number 4,830,028 (Chart G) describes a way to increase the nicotine content of low yield cigarettes from 1.66 percent to 2.9 percent nicotine by spraying on a 1, 3 or 5 percent nicotine salt.

The patent states the nicotine salt is used because added nicotine alone is unacceptably harsh or irritating to the user. Notice that great care is paid to the pH of the smoke because pH affects ab-

sorption of nicotine into tissues. This technology can increase content of tobacco by up to 76 percent and lower the pH in the process.

The next chart. U.S. Patent number 5,065,775 (Chart I) describes chemical methods using chlorofluorocarbons that can be used, among other things, to bring the tobacco blend containing 2.3 percent nicotine up to 5.2 percent nicotine. This technology increases the nicotine content in tobacco by more than 100 percent.

The next chart. U.S. Patent number 4,898,188 (Chart J) shows how to transfer nicotine by supercritical fluid extraction involving liquid carbon dioxide. An example in the patent shows that the technology can reduce the Burley tobacco from 3.56 percent nicotine to 0.88 percent nicotine and increase the flue-cured tobacco from 2.59 percent to 4.83 percent. This patent demonstrates that nicotine can be transferred in significant amounts from one type of tobacco filler to another.

Mr. Chairman, these patents illustrate that the cigarette industry has developed technologies that allow it to add or subtract nicotine from tobacco. The amount of nicotine present in cigarettes may therefore be a matter of choice, not chance.

Mr. Chairman, that prompts me to ask: How does the industry determine nicotine levels in various products? More importantly, why does the amount of nicotine in cigarettes remain at addictive levels? In fact, since the technology apparently exists to remove nicotine from cigarettes to insignificant levels, why does the industry keep nicotine in cigarettes at all?

The cigarette industry would like you to believe that it simply returns the nicotine that is removed when reconstituted tobacco is produced. It should be clear from what I have described that the technology that the industry may have available goes beyond such efforts. The industry may also tell you that it is adjusting nicotine levels to be consistent with established FTC yields. These are the amounts of tar, nicotine, and carbon monoxide that are measured for each cigarette product by a smoking machine. But in fact, patents were granted for adjusting nicotine levels before those FTC measurements were adopted. No measurements would prevent the industry from reducing nicotine below addicting levels or eliminating it all together.

Nicotine levels may be dictated in part by marketing strategies and demographics. Let me show you a reproduced copy of one smokeless tobacco company's marketing strategy. The products with the lower nicotine yield are found on the bottom and marketed as "starter" products. As you go up the chart, nicotine yields increase. And through advertising, the users are encouraged to "graduate"—their word, not mine—to products with higher levels of nicotine, marketing on the basis of nicotine delivery.

Why develop such a strategy? The cigarette industry may tell you that the purpose of nicotine is to provide flavor. Information suggests otherwise. A company's own book on flavoring tobacco lists about a thousand flavorants, but nicotine is not one of them. Some industry patents specifically distinguish nicotine from flavorants.

As we saw earlier, technologies have been developed specifically to mask the unacceptably harsh and irritating flavor of added nicotine. In fact, U.S. patent 4,620,554 uses the word "hazardous" to

describe the taste of nicotine. It shouldn't come as a surprise to anyone, the Merck Index, the authoritative encyclopedia of chemicals, describes nicotine as having an acrid, burning taste. Smokers apparently do associate the burning in the throat with nicotine's psychoactive effects and thus look for those sensory signals in a cigarette, but nonaddictive substances have been shown to produce those effects.

Why doesn't the industry use them instead? Why is nicotine in cigarettes? The research undertaken by the cigarette industry is more and more resembling drug development. I mentioned earlier the focus on controlling the pH of tobacco smoke because it affects absorption of nicotine. The cigarette industry has also studied the activity of added nicotine versus nicotine that occurs naturally and it has studied the potentially beneficial effects of nicotine on anxiety, heart rate, and behavioral performance tasks. Such research on the physiological effects of an active ingredient is a standard part of drug development.

Perhaps the most striking research undertaken by the industry is the quest for new nicotine-like chemicals with pharmacological properties that, and I quote from a patent, "are intended for utility as potential psychotherapeutic agents." The chart shows one patent that summarizes the effect of nicotine-like chemicals on tranquilization, sedation, and body tone of mammals.

Mr. Chairman, I would like to move on to the actual nicotine levels in cigarettes. FDA laboratories measured the amount of nicotine in several types of cigarettes. We analyzed three varieties of one brand; for example, highest, medium, and lowest. What surprised us was that the lowest one in fact had the highest concentration of nicotine in the cigarettes. Let me repeat that. The lowest one in fact had the highest concentration of nicotine in the cigarette.

I have read with interest the testimony that Mr. Spears, Vice Chairman of Lorillard Tobacco Company, will give this morning. He states that, and I assume he is speaking for the industry, we do not set nicotine levels for particular brands of cigarettes. He goes on to say that nicotine levels follow the tar levels.

The easy proof, according to Mr. Spears, is that both tar and nicotine on a sales weighted basis have decreased in the same fashion and in the same amount over the years. One question: If there is no manipulation of nicotine going on, why does the lowest yield cigarette I just showed you have the highest percentage of nicotine in it? If Mr. Spears is right, wouldn't the lowest yield cigarette have the lowest concentration of nicotine in it?

Furthermore, Mr. Spears says that the fact that tar and nicotine have decreased in parallel fashion over this time period, and I quote, "by the same amount" indicates that there has been no manipulation of nicotine levels. But when you look closely at the numbers from FTC's database for tar and nicotine levels in smoke since 1982, the earliest year for which the FTC-computed database is available, we do not see that kind of tar and nicotine content occurring in a parallel fashion and by a proportional amount over the last decade.

Let me show you the graphs describing the nicotine and tar changes from 1982 to 1991, the years for which the database is available. You will see from the chart (T) that the proportional

change in nicotine has not been the same as the proportional change in tar for each of the years from 1982 to 1991. In fact, these data suggest that the amount of tar over this time period has remained relatively flat while the proportional amount of nicotine has not. Rather, nicotine levels in smoke appear to increase over the last decade.

The next graph (Q) shows percent changes in nicotine and tar levels from their average 1982 levels for low-tar cigarettes. The next graph (R) displays the information for high-tar cigarettes. And the next graph (S) provides similar information for ultra low-tar cigarettes.

All three categories clearly suggest that tar and nicotine levels in smoke are not following parallel patterns over the last decade.

The final graph (U) summarizes in a different fashion the previous graphs by showing the nicotine/tar ratios are not identical in the three categories of cigarettes. Why not?

We feel these data call into question Mr. Spears's conclusion and require further explanation.

Mr. Chairman, the evidence I have presented today suggests that cigarette makers may intend the obvious, that most smokers buy cigarettes to satisfy their nicotine addiction. We do not yet have all the evidence necessary to establish cigarette manufacturers' intent. As we reconsider our traditional assumptions about nicotine in cigarettes, we will need to determine whether nicotine-containing cigarettes meet the statutory definition of a drug.

As I mentioned earlier, intent is a key issue. It should be clear, however, that in determining intent, what cigarette manufacturers say can be less important than what they do. The fact that the technology is available to reduce the nicotine to less than addictive levels is relevant in determining manufacturers' intent.

Clearly, the possibility of FDA exerting jurisdiction over cigarettes raises many broader social issues for Congress to contemplate. It could lead to the possible removal of nicotine-containing cigarettes from the market, the limiting of the amount of nicotine in cigarettes to levels that are not addictive, or restricting access to them, unless the industry could show that nicotine-containing cigarettes are safe and effective.

If nicotine were removed precipitously, millions of Americans would experience addiction withdrawal. Of course, a black market in cigarettes could develop.

On these issues we seek guidance from the Congress.

Thank you.

[The prepared statement of Dr. Kessler begins on p. 71.]

Mr. WAXMAN. Thank you, Mr. Commissioner. Dr. Kessler, without objection, I am going to recognize each member on this first round for 10 minutes; any subsequent round, for 5 minutes if it is necessary.

Dr. Kessler, you have laid out a really astounding picture, not only of the tobacco companies manipulating the levels of nicotine, but by doing that, manipulating the American people who take up cigarette smoking. We are not talking about a choice any longer if it is an addiction. They have the ability to manipulate the nicotine which evidently causes the addiction to smoking itself.

One of our colleagues said we have known for some time that they could deal with the nicotine levels in cigarettes, but I don't think any of us have any idea of the sophisticated techniques that the tobacco industry has had at its disposal to play around with these nicotine levels. They could figure out exactly the level needed to hook people, to get them addicted so that most people will find it very difficult to quit.

I found that astounding when you think 400,000-plus people die every year from cigarette smoking, all which that involves in terms of pain and suffering for the people and their families, and all the costs that are incurred for health care costs to treat them, to try to save them and prolong their lives, sometimes with some misery.

I really don't know what to say about such a thing. I guess we have to go through the technical questions of legality, whether this was intended or not for you to decide whether you have jurisdiction. It is a question also for those of us who are here as people's representatives, whether we should leave this industry on its own to be so cynical in manipulating the nicotine levels.

Let me just lay some things out to understand clearly what we are talking about.

Tobacco is an extremely serious health hazard. It killed 430,000 people last year; is that correct?

Mr. KESSLER. That is correct.

Mr. WAXMAN. Second, nicotine and tobacco is an addictive substance. It has all the hallmarks of addiction. Nicotine is why people who want to quit smoking can't quit; is that correct?

Mr. KESSLER. That is correct.

Mr. WAXMAN. Third, nicotine has drug-like qualities, it has physiological effects. In the words of the Food, Drug and Cosmetic Act, it affects the structure and function of the body; is that correct?

Mr. KESSLER. It certainly has those physiological effects.

Mr. WAXMAN. Until 1902, the Coca-Cola Company added cocaine to coke. Today, such a company would not think of adding cocaine or any other addictive substance to soft drinks.

Isn't it true that the Food and Drug Administration would not approve addictive levels of nicotine as an additive which could be added to food?

Mr. KESSLER. Right, Mr. Chairman. The Coca-Cola Company in that time period sent their coca leaves to the Shaffer Alkaloid Works in Maywood, N.J. to have them decocainized. We would not allow addictive substances to be in any product that we regulate without the most tight regulation.

Mr. WAXMAN. Coca-Cola Company removed cocaine——

Mr. KESSLER. Right before the 1906 Act.

Mr. WAXMAN. You testified that nicotine could be removed from cigarettes, and it is possible to duplicate the taste of nicotine.

I realize you are not ready to make a final decision, but are you aware of any significant, reliable evidence that would support the proposition that the manufacturers leave nicotine in cigarettes for any reason other than addiction?

Mr. KESSLER. No.

Mr. WAXMAN. Dr. Kessler, on the critical issue of the industry's intent, have you found any studies by the tobacco industry that

would support the proposition that nicotine is retained in tobacco for addictive purposes?

Mr. KESSLER. Mr. Chairman, I mentioned earlier about self-administration studies in animals that show that, in fact, nicotine is addictive. Self-administration, as I mentioned, in laboratory animals is a hallmark of a drug that has the potential to addict.

We have recently learned that a team of industry researchers carried out studies in the 1980's and reached similar conclusions several years before. The results were actually published by other scientists in the late 1980's. We understand that two manuscripts from industry scientists were submitted to a well-respected independent journal in 1983 and 1986 and accepted for publication.

The first was entitled, "Nicotine Is a Positive Reinforcer in Rats: Effects of Infusion Dose in Fixed Ratio Size." I will let Dr. Henningfield describe what that means in a second.

The second was entitled, "Intravenous Nicotine Administration in Rats: Effects of Mecamylamine Hexamethonium and Naloxone." The titles of these studies alone tell you the important criteria in determining that the rats self-administer nicotine; and again that is an important criteria—one of the important criterias in determining whether a substance is addictive.

Mr. WAXMAN. Are you saying, in other words, that the tobacco industry sponsored studies of animals that would indicate that nicotine was addictive to these animals, and that is the way we find out whether anything is addictive?

Mr. KESSLER. It is one of the hallmarks of whether a drug is addictive.

Mr. WAXMAN. What happened to these studies?

Mr. KESSLER. We have been told that both manuscripts were withdrawn by the researchers before publication. We have a copy of a letter from an editor of the journal to the researcher acknowledging the withdrawal of the second manuscript, and in that letter the editor repeats what he has been told by the researcher, that the manuscript is being withdrawn because the company has issued an injunction against publication of this paper.

Mr. WAXMAN. In other words, the tobacco industry sponsored studies on their own where they found out that nicotine was addictive; and before the public could know about it, they acted to suppress those studies?

Mr. KESSLER. Again, from the title, it says "Nicotine Is a Positive Reinforcer in Rats." That suggests positive findings that nicotine was self-administered in rats.

Mr. WAXMAN. The tobacco industry officials have stated over and over again they don't believe that tobacco is addictive. What you are telling us is that they knew from their own studies that tobacco—nicotine has an addictive quality, and they tried to suppress that information.

Mr. KESSLER. Mr. Chairman, I am not drawing any conclusions. I am telling you what we have learned about what studies were undertaken and what happened to those studies.

Let me let Dr. Henningfield——

Mr. WAXMAN. I have a limited period of time. Could you tell us what company sponsored those studies?

Mr. KESSLER. Mr. Chairman, I would be very happy to work with the committee. I am reluctant to do this today. Certainly if the committee does instructs, we will be happy to provide you with information.

The issues that we are addressing today are general issues about nicotine in cigarettes. I certainly don't want to—I understand the problem of not releasing the name is that I may, unfortunately, cast aspersions on other companies; and again, we will be happy to provide all the information to you, Mr. Chairman. I think that it is for your review. You can investigate further. You can see what the facts that we have are, and determine whatever intent may follow.

Mr. WAXMAN. We will work with you to receive that material, but you know of a study. You didn't learn of this through a confidential means, did you? You know of a study that was sponsored by the tobacco industry that was supposed to go into publication and wasn't?

Mr. KESSLER. We have a letter from an editor that states what I told you.

Let me also just allow Dr. Henningfield—we also have confirmation—

Mr. WAXMAN. Dr. Kessler, was this sponsored by the industry or was it sponsored by a cigarette company?

Mr. KESSLER. It was a cigarette company.

Mr. WAXMAN. And why can't we know the name of that company?

Mr. KESSLER. Again, Mr. Chairman, I would be happy to work with you and give you our documents. I am not prepared at this time to do that. I don't want today—I cannot come here to talk about it. I was very careful in my presentation not to focus on specific brands or specific companies, and I would really rather not get into that today.

Again, we would be happy to give the committee the information, and certainly you can do whatever the committee would like to do with it.

Mr. WAXMAN. I have run out of time. Do you have something briefly to add? Maybe we will come back to you.

Mr. HENNINGFIELD. I could just confirm that in fact in the early 1980's a number of us in the field were aware that one of the tobacco companies was sponsoring such drug self-administration research. One of the tobacco company investigators sent me one of the resulting manuscripts. This is something that is often done by scientists; they exchange manuscripts and to let others know what they are doing in the field.

I had marked it in my files as an unpublished manuscript, and therefore would not have cited the manuscript in my own literature reviews. When I called the investigator to ask him what the status of it is and if I could cite it in my literature reviews, he told me that he would not be able to publish it, so that I would not be able to cite it. Furthermore his words, to the best of my recollection, were that the lawyers of the company had discovered that the investigators and colleagues were doing this work and that it showed that nicotine looked like heroin, and therefore that such work shouldn't be going on and it should not be published.

Mr. WAXMAN. Was this in any way illegal for a company, that you know of?

Mr. HENNINGFIELD. I am not familiar with any of the legalities, just the basic science. This was a good basic science study. It did demonstrate that nicotine served as a reinforcer for the rats. The proper experimental controls were done. These included the interesting standard manipulations to look at the dose and see how much the animals would work for each dose.

[The following letter was received:]

DEPARTMENT OF HEALTH & HUMAN SERVICES,
Baltimore, MD, May 3, 1994.

Hon. HENRY A. WAXMAN,
Chairman, Subcommittee on Health and the Environment,
Committee on Energy and Commerce, House of Representatives,
Washington, DC.

DEAR CONGRESSMAN WAXMAN: With reference to the unpublished manuscript by Dr. Victor J. DeNoble, et al., entitled "Nicotine as a positive reinforcer in rats: Effects of infusion dose and fixed ratio size," I made an error that I would like to correct for the record. During the March 25 hearing I stated that I had not cited the DeNoble et al. paper in my own literature reviews. However, I have recently been reminded that I did make reference to the DeNoble work in a book chapter that I wrote.

Upon receiving the manuscript from Dr. DeNoble in 1983, I made reference to his important finding in several papers that I was working on at the time. Later, upon learning from Dr. DeNoble that his paper would not be published, I deleted reference to it from manuscripts that had been submitted (or were to be submitted) to scientific journals for publication. What I had quite simply forgotten about was that I had also made reference to the DeNoble work in a book chapter entitled "Behavioral pharmacology of cigarette smoking," published in *Advances in Behavioral Pharmacology*, edited by T. Thompson, P.B. Dews and J.E. Barrett, Academic Press, Inc., 1984. I apologize for this oversight.

Sincerely,

JACK E. HENNINGFIELD, PH.D., *Chief, Clinical Pharmacology Branch.*

Mr. WAXMAN. Do you know any reason why we shouldn't know the name of the company that sponsored that study?

Mr. HENNINGFIELD. I defer to Dr. Kessler.

Mr. WAXMAN. Is there any reason why we shouldn't know that information?

Mr. KESSLER. Mr. Chairman, we would be happy to work with you.

Mr. WAXMAN. If you are going to give it to us later, why not give it to us now?

Mr. KESSLER. I would prefer to present to the committee the information, and then you can do what you would like with it.

Mr. WAXMAN. Mr. Bliley.

Mr. BLILEY. Dr. Kessler, in your February 25th letter you state, and I quote, "In fact, it is our understanding that manufacturers commonly add nicotine to cigarettes to deliver specific amounts of nicotine," unquote.

Dr. Kessler, this statement is unequivocally false. In fact, in the processing of raw tobacco into cigarettes, the nicotine levels in cigarettes are reduced as compared to the raw unprocessed tobacco product. In the manufacturing process, there is no replacement of lost nicotine.

Let's first address the question of whether cigarette manufacturers spike or add nicotine to their product.

Chart two, I would like you to examine this graph which is taken from the 1989 Surgeon General's report. This graph documents the

decline of nicotine and tar from the 1950's to the 1990's; for both tar and nicotine there has been a 69 percent reduction.

This graph also shows that nicotine levels are a function of the tar levels in tobacco. When tar levels are set, nicotine levels follow. As manufacturers have reduced tar levels over the years, nicotine levels have concurrently fallen. That is why tar and nicotine levels have been reduced by exactly the same amount, 69 percent.

Therefore, this graph demonstrates correlation between the reduction of tar and nicotine levels.

As I am sure you know, correlation is a very common statistical measure of the dependence between two factors. For example, Scholastic Aptitude Test scores are strongly correlated with first-year grades in college. In other words, a high SAT test score is an excellent predictor of success in college.

In statistics, correlation coefficients of 0.50 are evidence of significantly strong relationships. In this graph, the correlation is very close to one, meaning that the relationship between tar and nicotine is very, very strong.

What does this mean? First, that nicotine levels follow tar levels; second, that no nicotine manipulation has occurred in the manufacture and process. Why? Because if nicotine was being added back into cigarettes the data would have shown one of three things: Nicotine levels would have remained relatively constant over the 40-year period while tar levels would have declined significantly; second, nicotine levels actually have declined very little compared to the 69 percent reduction in tar levels; finally, nicotine levels could have increased while tar levels declined.

In all these cases, the correlation between the levels of nicotine and tar would be very weak or even negative. Instead, this data shows an almost perfect positive correlation. In other words, nicotine is not being added.

Chart three, what about the tar and nicotine levels in 1994? This table presents the correlation analysis of the latest tar and nicotine results to be reported by the Federal Trade Commission. The correlation coefficient of the amount of tar and nicotine in domestic brands is 0.975. This is essentially a perfect correlation between the levels of nicotine and tar. Again, this is very strong statistical evidence that nicotine is not being manipulated.

[The charts follow:]

CHART 1

"In fact, it is our understanding that manufacturers commonly add nicotine to cigarettes to deliver specific amounts of nicotine."

-- February 25, 1994 letter
from David Kessler to
Coalition on Smoking OR
Health

Mr. WAXMAN. Thank you, Mr. Bliley.

Before calling on Mr. Synar to go through his questions, I want to recognize the distinguished Chairman of the Energy and Commerce Committee, Mr. Dingell.

Mr. DINGELL. Thank you, Mr. Chairman, for this courtesy. Mr. Chairman, I came down to ask no questions, but I wanted to commend you for having this hearing. I think you are going into an extremely important question, one which is a matter within the responsibility of this committee and one which is a major public health concern.

And Dr. Kessler, I want to commend you and your associates at the table there for your assistance to us. You have approached an extremely important question, in what I think is a highly professional, scientific, and decent way. I want to express my commendations to you, as I do to the chairman for holding this hearing today. This is an important question, and I will be following it very closely as the committee proceeds with its business on this matter.

And Mr. Chairman, I thank you, and I thank you, Doctor, for your kindness to us today.

Mr. WAXMAN. Mr. Synar.

Mr. SYNAR. Thank you, Mr. Chairman.

And Dr. Kessler, thank you. I think, as the chairman of our full committee just said, this is very important. I don't think I would be exaggerating to suggest that we have just witnessed some of the most historic testimony in the history of Congress on any subject. And you and your staff who have been working on this, not just in the last month but in the last year, are to be commended for the courage and the leadership that you are taking on this.

I want to go back to something Chairman Waxman said: whether or not nicotine is a drug will somehow be determined on looking at the manufacturer's intent. You also go on to say that you are concerned about the industry's manipulation of that nicotine.

That does not mean, does it, strictly speaking that they spiked it to higher or more pure levels, but that they just changed the level? Is that not correct?

Mr. KESSLER. That is correct, Congressman. Our concern is the control over the nicotine levels and why those levels are being set the way they are.

Again, you can change nicotine levels either by adjusting endogenous amount of nicotine or you can achieve adding exogenous nicotine. In the end, it is irrelevant how you increase the nicotine.

It is almost irrelevant. There is some tobacco industry research that I have seen that suggests exogenous—suggests—it is old; it is in the literature that suggests that exogenous nicotine may, in fact, be a little more active. I would be interested in seeing that data, but it makes no differences for the purposes of the Food and Drug Administration.

Mr. SYNAR. The chairman asked me to ask you what those two terms mean.

Mr. WAXMAN. Will the gentleman yield?

Mr. KESSLER. Let me use an analogy. It is something that has been in the news lately. It is the Big Bertha example, BST, which has been in the news.

You can take the genetically derived bST and add it to a cow, or you can breed a cow like Big Bertha that just has more bST in the animal. Exogenous has to do with applied from without; endogenous has to do with applied from within.

Mr. WAXMAN. Will the gentleman yield?

In other words, whether it is sprayed on and added to the tobacco or whether it is a mixture of a high-nicotine blend with a low-nicotine blend; is that what we are talking about?

Mr. KESSLER. Absolutely.

But biologically, Mr. Chairman, the nicotine—the nicotine that ends up in the bloodstream is what we are concerned about. You can raise nicotine levels either way, so its effect on structure and function obviously can be affected either way.

Mr. SYNAR. Second, Dr. Kessler, could you tell us how the FDA regulates nicotine in other products, such as nicotine gum or nicotine patches or other things that it appears in?

Mr. KESSLER. Andrew, if I could have the chart on the products that we have approved.

Congressman Synar, I think this chart will show you the names of the products that we have approved, the ingredient base, the strength, the dosing intervals. We have approved those under the drug provisions of the Act.

Mr. SYNAR. That, I think, is an important point because, as you know, one of the things that the industry would have us believe is that the only option available to us is to ban the product. But we are presently regulating nicotine in many products, which is something very short of the kind of ban which they claim is the only alternative.

Mr. KESSLER. Congressman, those products have nicotine for a therapeutic effect, obviously to prevent the withdrawal symptoms that can occur from smoking cessation. I guess you can view the cigarette as the same, having nicotine to prevent the withdrawal symptoms, so there are similarities. But I should also make sure that the subcommittee understands that there are differences.

Certainly these products have the therapeutic claim that is attached to them.

Mr. SYNAR. I would like to go back to one chart that you used in your presentation. I think it is this one right here where you show examples of the highest, middle, and lowest 100's and the percentage of nicotine in each one of those products.

Mr. KESSLER. It is an example of three different varieties from one brand family. Our lab ran those numbers. We actually had several labs run those numbers; depending on how many hours of the extraction, you can get somewhat different numbers, but they are all in the same proportion. And all the numbers we have seen have the lowest-yield product having the highest concentration of nicotine. And that surprised me, Congressman.

Mr. SYNAR. That surprised me, too, because it flies in the face of industry statements that they don't put in different levels of nicotine with respect to different levels of cigarettes within a chain.

Mr. KESSLER. This is concentration.

Mr. SYNAR. I understand that.

What disturbs me even more is if one takes that chart and cross-tabs it with the type of advertising for those various products, one

would be led to believe by the industry that the smoking of the lower tar and nicotine cigarettes is safer.

And yet, this chart flies in the face of that, that you may, indeed, be subject to even more nicotine in a low-tar cigarette that has been advertised as being safer.

Mr. KESSLER. The lowest-tar cigarettes usually have less tobacco in them. The absolute amount of nicotine, the nicotine may be the same in the highest, medium or low, but the concentration is highest in the lowest tar cigarette so there is more nicotine proportionally in that tobacco versus in the highest brand.

But you raise a most important question, and that is, what is a consumer who wants to reduce levels supposed to do? Dr. Henningfield—in talking about this, he draws a analogy to food labeling and what does “lite” mean? And unfortunately, there is not a correlation between FTC yield numbers and what is actually absorbed in the body.

And if I could just have the FTC charts, the reason for that—it is not that the machine isn’t working and it is not that the FTC is not doing and overseeing the tests correctly. They are. They are doing a good job.

The issue is that the humans don’t smoke like the machines, the ones at the FTC.

Mr. SYNAR. The one that Mr. Bliley put up there.

Mr. KESSLER. There are a number of reasons why the low-yield cigarette really in many ways is a myth. One, the serving size; if you hold the analogy, the puff volume, is not the same. Smokers compensate.

There are also certain ways that the manufacturers can—under the manufacturer’s control that can reduce the level below the rating for which the FTC rates cigarettes. For example, the placement of ventilation holes on the cigarette. I don’t think most people even know that there are ventilation holes, and when you put the cigarette in the machine, the machine doesn’t cover the ventilation holes.

But, in fact—I think there is a picture, Andrew, of the actual ventilation holes. The cigarette with the holes, if you can find it. The machine doesn’t cover those holes. You can see the cigarette, and there is a magnification. This is one of the ways you get a low-yield cigarette it is not by reducing the nicotine in the tobacco rod necessarily.

One of the major advances, one of the technologies is to increase the air dilution. And these holes are one of the ways to increase, put more air into the smoke, thereby reducing the amount of active ingredients in the smoke. But the machine doesn’t cover those holes.

Kozlowski in the early 1980’s did a number of studies, and he found that between 30 and 60 percent of people cover those holes with either their lips or their fingers. And some don’t even know that they are doing it; and when you cover those holes, you end up getting more of the nicotine that is in that tobacco rod.

Mr. SYNAR. So the physical building of the cigarette, which then can take advantage of the advertising that it is lower tar and nicotine, is defeated by the mere using of the fingers and the lips.

Mr. KESSLER. Let me show you another one.

There is another way to get a lower FTC rating than smokers actually get.

Part of the filter paper—and Grunberg has done this work—extends out over the smoking rod. It is called the overwrap. There is actually tobacco under that overwrap. And the smoking machine, the instructions are to stop three millimeters before that overwrap. But smokers can smoke that tobacco.

If you are a cigarette manufacturer and you wanted to have a yield that was low, but still had enough tobacco in there for whatever reason, what would you do? That overwrap, as Grunberg has documented in the Surgeon General’s reports, has increased.

The FTC described this as sort of a Type 2 error. It is not that there is anything wrong with the smoking machine; it is just that there is technology that has been advanced for whatever reason that undermines the usefulness of the machine measurements.

One other technology is to increase the burning rate, which decreases the number of puffs the machine takes. All those technologies basically mean that what you are getting in your body doesn’t correlate, and Benowitz did very eloquent work in 1983 and subsequent years that shows what you are getting in your body doesn’t correlate with the FTC yields; and I think there is room for improvement so that people who want information can get reliable information.

Mr. SYNAR. Thank you, Dr. Kessler.

Mr. WAXMAN. Mr. Wyden.

Mr. WYDEN. Thank you, Mr. Chairman.

And, Dr. Kessler, let me commend you, as my colleagues have done, for an excellent job. I suspect folks at home in Oregon are not following all the nuances of exogenous and endogenous and the like, but I want to tell you what is the bottom line for me and see if you agree with this proposition.

The bottom line to me is that it appears that nicotine is taken out during the production process and then deliberately put back in later on. And when it is deliberately put back in, it, in effect, hooks the American public and hooks the smokers of our country. Would you agree with that?

Mr. KESSLER. You can hook someone, Congressman, just by taking 10 different tobacco blends and adjusting the levels. There is no difference whether it is reconstituted, or tobacco extract, or you are mixing the blends. In the end, the issue is how are those levels being controlled? You can increase levels, you can decrease levels many different ways.

What concerns us is that the levels of nicotine in cigarettes is in excess of what is necessary to create and sustain an addiction. It is irrelevant to our analysis how the nicotine—whether it is the reconstituted tobacco, or whether it is the blend, the issue is how is that level set and why is that level set in such a way that it is in excess of what is necessary to addict—to sustain and support an addiction?

Mr. WYDEN. In today’s Washington Post, Steven Parrish, the Vice President of Philip Morris, makes the admission that Philip Morris is adding nicotine to cigarettes. Is this, on its face, an admission that cigarette manufacturers are in the drug business and therefore subject to regulation under the 1938 Act?

Mr. KESSLER. Congressman, I tried very hard not to deal with specific companies today, but to respond to this comment—

Mr. WYDEN. Let's set aside then Philip Morris, even though they said it in *The Washington Post*.

If a drug company admits that they are adding nicotine to cigarettes—this is what I am asking, in a hypothetical case—isn't that an admission that they are in the drug business and therefore subject to regulation under the 1938 Act?

Mr. KESSLER. I am sorry, if you can ask the question again.

Mr. WYDEN. If a drug company admits that they are adding nicotine to cigarettes is that an admission that they are in the drug business and therefore subject to regulation?

Mr. KESSLER. Andrew, if I could get the definition of drug, this is what it comes down to. There are three parts of the definition of drug. One has to do the formularies; that is not at issue here. The relevant two sections—something is a drug either of two ways, for all practical purposes: an article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease. Does that apply to nicotine in cigarettes?

It certainly is possible to argue addiction is a disease. And then the question is, is the article intended for the mitigation of a disease?

But I think the harder question for the Agency to deal with is the third definition. And that is—something can be a drug if it is an article other than food intended to affect the structure or function of the body.

So is a psychoactive effect affecting the structure and function of the body? Is an addictive effect from the psychoactive effect affecting the structure and function the body? Again, it is that word "intended" that the Agency pays a lot of attention to.

Mr. WYDEN. If it looks like a drug and acts like a drug, it sounds to me like a drug. And I think that is essentially what you have spelled out for us today.

Now Philip Morris is quoted in the papers this morning as saying that no powerful extract containing nicotine is added in its manufacturing process. Can you tell us again in a generic way, apart from any company, what kinds of powerful tobacco extracts are added in the manufacturing process?

Mr. KESSLER. Congressman, I had an option and I declined that option; I had an option to sign a confidentiality agreement and to see what substances are actually in cigarettes, to see the list. I declined to exercise that option. I did not want to be bound by information that I could not share with the American public.

Mr. WYDEN. Well, you know, this industry says that it has got nothing to hide. Why don't we just change the law and make that ingredient list that I held up public? Wouldn't that be in the public interest?

Mr. KESSLER. Congressman, I think that is for the Congress obviously to decide.

Mr. WYDEN. What would be your personal opinion?

Mr. KESSLER. I worked very hard. I spent 3 years of my life trying to let people know what is in food, to give them the whole story. I think we have to be careful, though. Nothing is more dan-

gerous than what is occurring naturally that I know about in cigarettes.

Yes, I understand the focus on any additives, but I can't think of any substances more dangerous than what is occurring there naturally.

I think you also, Congressman, need to look, and I think one of the questions that requires evaluation is, what about manipulation of natural ingredients? Because in the end, natural ingredients could be—certainly in cigarettes there are very few things that are more toxic.

Mr. WYDEN. You make a good point. What I am concerned about is this pattern of secrecy and pattern of nondisclosure, and I am going to push to make this list public.

Over the years, the tobacco industry has spent substantial sums, millions, to fund research to dispute the kinds of health risk claims that you are making today. Are you aware of research done by the tobacco industry that disputes your claims, and what is your opinion of the quality of tobacco industry research, again in a general sort of way?

Mr. KESSLER. Congressman, I referred to the chairman about two studies that were undertaken that were not published. Dr. Henningfield, who saw the paper that indicated that nicotine is a positive reinforcer, thought—I don't want to speak for you, Jack. Our understanding is that those papers were accepted by a prestigious, independent journal. They were never published, unfortunately. It is very hard to comment broadly.

There is—Andrew, do you have the chart on the myths about tobacco? There are some myths, Congressman. And I just think, again, everyone needs to understand that these are myths.

One, tobacco is not dangerous; two, nicotine is not addictive; three, people who smoke low-nicotine cigarettes get less nicotine than people who smoke high-nicotine cigarettes. That a cigarette is natural tobacco rolled in a paper sleeve. Smokers know what they are smoking. Those are myths about tobacco. I can go on, but you can read the list.

Mr. WYDEN. Let me just wrap up with some questions that were asked in the press recently that I think really summarize it for me.

You have said that nicotine has been deliberately added to tobacco products; have you not?

Mr. KESSLER. Congressman Bliley has talked about tobacco extract. He has talked about other processes. The issue before us is the significance of whatever tobacco is in there. I don't think anyone is disputing the fact that tobacco extract is used. We have seen it sold. Tobacco extract has nicotine, and it is being used.

Mr. WYDEN. Let me finish just with this, then.

So nicotine is being deliberately added, and it is being added, in your opinion, at levels that are known to be addictive; isn't that correct?

Mr. KESSLER. The issue for the Agency is the control and manipulation of the nicotine level. I think that needs to be reiterated and reiterated, over and over again. The issue is whether the levels of nicotine—either added from tobacco extract or other means, or naturally—are being manipulated to sustain an addiction. That level that we see in cigarettes is in excess of the addictive level.

Mr. WYDEN. Thank you, Mr. Chairman.

Mr. WAXMAN. Thank you, Mr. Wyden. I am going to follow up on that and take a second round.

It is obvious that the level is being controlled and manipulated. If we know that nicotine can be removed from tobacco completely, if we know it can be removed and it is not being removed and we know that the tobacco industry, or at least one company, did a study that told them that nicotine was the addictive quality in their product, if there is no reason for nicotine other than for addiction, then all this manipulation is to addict people to smoking.

People are being manipulated. I don't see that there is any other conclusion that we could reach.

Isn't that true, Dr. Kessler, at that point?

Mr. KESSLER. Why is nicotine at levels that are addictive in cigarettes? That is the question that needs to be answered.

Mr. WAXMAN. And I want to commend you on your testimony. This is really very powerful testimony. I think it is historic. Never in this country have we understood what was going on with the tobacco industry, and we are only getting a little whiff of it, so to speak, a little bit that we are seeing from your testimony.

We know the tobacco companies have tobacco that has nicotine in it. We have always thought that. But the tobacco companies can exogenously, endogenously manipulate and play with those levels. They spray it on.

Mr. KESSLER. Andrew, do you have the reference cigarettes over the last number of years, over a period of time? You think that it is just tobacco leaves in a cigarette. These are just four examples, and they are done as reference cigarettes. And you can see that you can achieve, you have a lot of different tools to achieve whatever level of nicotine you want.

There is lamina, there is stem, there is puff, there is reconstituted. There are different types of tobacco. You can set nicotine levels with great care.

Mr. WAXMAN. So they can do this—let me ask you about some of these points, because those patents are really astounding. You indicated they can change the blend. You indicated that they can take nicotine and spray it on later.

Mr. KESSLER. Patents shows that they can do that, yes.

Mr. WAXMAN. The patents show that they can do something with the filter; isn't that correct? They can add nicotine to the filter itself?

Mr. KESSLER. Andrew, do you have the chart of the patent on the filter? I was a little surprised to see patents that actually had as their purpose to add nicotine to other parts of the cigarette. Why would you want to add nicotine to the filter? Why would you want to add nicotine to the wrapper? I think it raises questions.

Again, Mr. Chairman, it is very important that we be careful. These are patents. And I cannot sit here today and tell you which patents are—

Mr. WAXMAN. The point is, you can't tell us whether they use these patents, but it shows that the industry has carefully looked for ways of playing around with the nicotine levels in their products and they have even added it potentially through the filter paper itself.

No one could argue that there is a natural occurrence of nicotine in the paper, they may say that for the tobacco.

They can spray it on. They can add it to the filter paper, they can enhance the contents with a liquid. They can take an extract. This, to me, is absolutely astounding.

Mr. KESSLER. Again, I just need to be careful that these are patents. I want to underscore that.

Mr. WAXMAN. It shows the capability. But it shows that they were interested in developing that capability.

You have indicated that there is a company that you know of that did studies in the 1980's that must have led them to understand that nicotine is addicting.

Mr. KESSLER. Self-reinforcing in rats.

Mr. WAXMAN. Self-reinforcing in rats is the way that we decide whether a substance is addicting. If they knew that nicotine was addicting and they could add and play with the nicotine levels, they knew that they could get people hooked on tobacco.

You are going to give us that information about the name of the company, and unless you can give me a reason not to reveal that publicly, I plan to make that public because I think we ought to know a company that may well be telling us they never knew about tobacco nicotine being addicting. I would like to have their response as to whether they knew it or not, based on the fact they funded a study and then suppressed that very study.

Mr. KESSLER. Again, we will give you the facts that we have, and you can assess them and do any investigation.

Mr. WAXMAN. Thank you Dr. Kessler.

Mr. Bliley.

Mr. BLILEY. Dr. Kessler, it may be well known that denatured alcohol, number 4, SD-4 trade name, and certain tobacco flavors used during the manufacturing process contain minuscule quantities of nicotine. However, the total contribution of nicotine from these two sources is so small that it cannot be detected in the tobacco by standard laboratory methods and has no effect whatsoever on the nicotine delivery as determined by the Federal Trade Commission.

Let's first examine the effect of alcohol. Alcohol is used as a solvent and carrier for flavors in the cigarette industry as well as in the food and beverage industry. The denatured alcohol used is specifically denatured alcohol number 4, which is specifically approved by the Bureau of Alcohol, Tobacco and Firearms under the Federal regulation 27 CFR section 21.38.

The alcohol is denatured with small amounts of nicotine sulphate for the sole purpose to render it undrinkable. The graph shows the relative quantity of nicotine indirectly added to tobacco from the use of SD-4 alcohol. In processed tobacco, there are approximately 15,000 parts per million of nicotine. The contribution from alcohol is on the order of two parts per million; two parts per million of nicotine is too small to be measured in the final product.

Dr. Kessler, does FDA consider the use of denatured alcohol to be adding nicotine to the final cigarette? Is your suggestion that manufacturers may be spiking their cigarettes based on the use of denatured alcohol?

Mr. KESSLER. I have never said that, Congressman. I have never used the word "spiking." I have never even talked about denatured alcohol.

Mr. BLILEY. Then how did you arrive at your statement to the smoking people on February the 25th that the manufacturers may be spiking their cigarettes?

Mr. KESSLER. First of all, I didn't use the word "spiking," Congressman, and I would be happy to go through my testimony again, but it was rather lengthy.

Mr. BLILEY. All right, I will go through it, too; and if I find it, I will be back in touch with you.

When you were—at the invitation of Philip Morris, when you sent your people down to their plant in Richmond, did they observe anybody adding nicotine to the cigarettes?

Mr. KESSLER. Mr. Chairman, if you would like me to talk about one company, I would be happy to do that, but I am trying to stay away from talking specifically about individual companies. Philip Morris was very kind. They allowed us in for a courtesy visit. Our people sat and talked and learned a lot about the tobacco industry. I would be happy to share that with you. But again I am not prepared to do that today.

We have taken certain samples, we have learned certain things and talked to certain people. I think it is very important before we reach any conclusions to the questions that we raise today, we need not to just talk to any one company. We need to know what is going on in the industry across the board.

Mr. BLILEY. Thank you, Mr. Chairman.

Mr. WAXMAN. Thank you, Mr. Bliley.

Mr. Synar.

Mr. SYNAR. I might remind all of those that are listening, who think that we are beating up on the industry, that the chairman of this subcommittee invited both Philip Morris and R.J. Reynolds to be with us; and as the chairman pointed out, they chose not to do so, which speaks volumes about their interest and sincerity in the issue.

Dr. Kessler, you said on the very last page of your testimony, and I think it is a very important statement, "in these issues we seek guidance from Congress."

Let's summarize, if we can, really what this debate has come down to. You really have two options if you determine nicotine is a drug. You will have to ban the product unless it can be shown that it can be applied safely and effectively in curing some type of disease, or you will be able to regulate it; is that correct?

Mr. KESSLER. The tools are limited. Yes.

Mr. SYNAR. And so what you need from us is some guidance on what we think is appropriate for this product?

Mr. KESSLER. We have asked for that guidance, Congressman.

Mr. SYNAR. Many of us who have been engaged in this issue, Mr. Waxman and Mr. Durbin and Mr. Wyden and I have said that banning this product would be cruel and unusual punishment to the 50 million smokers in this country, to tobacco users, because the evidence—unsurmountable evidence now, is that they are addicted to a very serious drug. That is why we have favored the legislation

that Mr. Waxman and I, and Mr. Wyden and Mr. Durbin have been involved in.

Could I get your opinion on that legislation and whether or not you favor the basic principles that are behind it? Do you favor listing ingredients and chemical additives on the product of tobacco?

Mr. KESSLER. Congressman, I apologize for this, but as you know, the Food and Drug Administration, our job is to deal with the questions within our jurisdiction. Commenting on legislation is not something that I do as an Agency head. That is left, obviously, to the Secretary. So I apologize; I am not trying to not be as forthcoming. I am just not able to comment on any specific legislation.

Mr. SYNAR. Let me ask you this, then. Clearly if you do find nicotine to be a drug, it is probably, based upon the evidence that you presented today and other evidence that is available, going to be impossible to prove that it can be consumed safely. We know that the mere consumption of two cigarettes a day increases the chance of heart disease and cancer by 50 percent.

We have favored an approach for the FDA that would not define it as a drug or food product, but create a new, unique status. Is that a way to accomplish the goal of avoiding a ban, but getting the type of regulatory authority that we need in order to protect the public?

Mr. KESSLER. We understand the enormous social consequences that could attach to a decision to exert jurisdiction. And it is because of those enormous social consequences that we are seeking guidance.

There are those at the Agency, I must tell you, Congressman, that have a hard time believing that an Agency that is charged with making sure that there are safe and effective products on the market would ever find nicotine-containing cigarettes for anyone to establish that they are safe and effective. Maybe that could happen. Maybe there are levels below which the nicotine is not addictive and there can be an argument made.

But you are right. There are enormous social consequences. And that is why we are here today to seek your guidance.

Mr. SYNAR. Thank you, Mr. Chairman.

Mr. WAXMAN. Thank you, Mr. Synar.

Mr. Wyden.

Mr. WYDEN. Thank you, Mr. Chairman.

Dr. Kessler, just one other area I am interested in, and that is this matter of clear direction from the Congress. You have said, for example, and I quote, "Should the Agency make this finding based on an appropriate record or be able to prove these facts in court, it would have a legal basis to regulate these products."

Now, is that something you are going to go ahead with anyway? Or does Congress have to pass a law and say, Dr. Kessler, this is a drug, have at it?

Mr. KESSLER. Congressman, my job is to enforce the statute and the statute has the FDA making the decision of whether to exert jurisdiction. Let me be clear though that I think there are a lot of questions. I have shown you some data.

There are many issues that we don't fully understand. Philip Morris was very kind to allow us in for a day and a half, but there are many companies and there are still a lot of questions that need

to be answered. A lot more fact-finding. I hear Congressman Bliley using words like spiking—there is a lot more information that this Agency needs to understand and a lot more data.

Once we have that data, we need to assess. Also, I don't think we have the answers yet on what the public health consequences would be of reducing or eliminating nicotine. We need to understand that issue. If the Agency were hypothetically to exert jurisdiction, how should nicotine be regulated? What is the right way?

If you lower the dose of nicotine just a little, people may end up smoking more cigarettes. If you lower it below addictive levels, maybe no one will smoke. So the question becomes how should nicotine be regulated, and I don't think that we have thought through that or the public health community or the regulators or the Congress. I think we need to do work in that area.

Mr. WYDEN. My only point here is that I think it is a mistake for the Food, Drug and Cosmetic Act to be silent on this issue. I would rather see us pass a Synar bill and say regulate. If we can't get that passed, I hope you will go forward and try to build a record, play out the facts to show that this is a drug, and let me commend you on a first-rate job.

I think this is a hearing that the country is going to look back on in the next century and say this is a hearing that made a difference for our kids and grandkids and I commend you for it.

Mr. WAXMAN. I want to thank you as well. I want to close this part of our hearing today by playing the following statement out for maybe later witnesses to comment.

What you have told us very clearly without any controversy is that nicotine is addicting, it is the reason people continue to smoke. When kids get started, they get hooked. We have over 400,000 people die each year from smoking tobacco. This nicotine addiction is something we now know that at least one tobacco company knew about, and I believe they all knew about it. They carefully regulate the amount of nicotine in this cigarette product, and it seems that the major reason this manipulation of nicotine takes place is to assure there is enough there to addict people.

I can't understand why we allow cigarettes with nicotine at all if it doesn't add to the flavor, and it only adds to the addiction of it. You may or may not have the legal authority to insist that nicotine be removed.

We certainly have the legal authority to impose that on the industry, and I would like to know from them why they would insist on having nicotine in their product at any level if it only serves the purpose of addicting people to that product.

I wish the tobacco company executives were here so we could ask them directly. I would like to know from the Philip Morris Company that filed a lawsuit yesterday charging that ABC television should pay them \$10 million in damages because they reported the fact that nicotine is manipulated in tobacco.

I would like to know from Philip Morris, and I wish the head of Philip Morris had accepted our invitation, why they allow any levels of nicotine whatsoever, and I want to hear from other witnesses today what they have to say about this issue because it seems to me that is one of the core questions that is before us. You have

given us incredibly powerful testimony, and I very much appreciate your being here.

Mr. KESSLER. Thank you, Mr. Chairman.

[Testimony resumes on p. 138.]

[The prepared statement and supplemental charts of Dr. Kessler follow:]